Statement of Basis

Application for the Issuance of a Registration for Particle Accelerators

Fresenius Medical Care
475 West 13th Street
Ogden, Utah 84404

February 10, 2005

Purpose

The purpose of this Statement of Basis is to describe how the applicant, Fresenius Medical Care (Fresenius), has met the requirements of R313-16-231 of the Utah Radiation Control Rules (URCR). These requirements are in addition to the requirements of R313-16-230, "Registration of Radiation Machines." The applicant submitted a completed form DRC-10, "X-ray Machine Registration Application", to the Utah Division of Radiation Control (DRC) on November 17, 2004 as well as additional information required by R313-16-231. Additional information regarding the application was submitted to the DRC in a letter received February 8, 2005.

Summary of Application Proposal

Fresenius Medical Care manufactures products used in patient dialysis procedures. These products must undergo a sterilization process to make them safe prior to their use. Currently, Fresenius sends their manufactured products to sterilization facilities operated by other companies. Fresenius proposes to build and operate their own sterilization facility to be located at their manufacturing facility located in Ogden, Utah.

The facility will use two 10 MeV linear accelerators to produce a "cone" of energetic electrons that will be used to sterilize their products. The linear accelerators will be housed in an enclosed room (sterilization cell) that will be designed to prevent access into the room while the linear accelerators are operating, and will provide protection to workers and the public from any radiation produced by the linear accelerators. The facility will be designed to safely operate as many as four linear accelerators at a time. Fresenius will ensure that the individuals operating and maintaining the sterilization facility are properly trained in the safe operation of the facility.

R313-16-231(1)

"In addition to the requirements of Section R313-16-230, a registrant who proposes to use a particle accelerator shall submit an application to the Executive Secretary containing the following:"

R313-16-231(1)(a)

"Information demonstrating that the applicant, by reason of training and experience, is qualified to use the accelerator in question for the purpose requested in a manner that will minimize danger to public health and safety or the environment;"

Basis:

Fresenius has trained the plant safety officer as a radiation safety officer (RSO), and plans to hire a scientist with experience using electron beam (E-beam) equipment who will also be trained as an RSO. Currently, Fresenius monitors the sterilization activities of their medical products conducted at third-party facilities. The company plans to train four primary and four alternate operators of the E-beam equipment.

Fresenius has also chosen an E-beam equipment vendor that can provide full support in the building and during start-up of the facility. The vendor owns and operates three E-beam sterilization facilities, and has successfully installed 21 such systems worldwide. The vendor's E-beam systems have over 300,000 hours of operation. The safety system employed by the vendor includes computer-controlled interlocks, redundant hardware systems, and appropriate operating procedures. The vendor will tailor its operating procedures to meet the needs of Fresenius, and will also train Fresenius employees in the medical device sterilization process and use of the E-beam equipment.

R313-16-231(1)(b)

"A discussion which demonstrates that the applicant's equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or the environment;"

Basis:

Fresenius will be installing two horizontally-mounted s-band electron linear accelerators in a specially-designed facility that is designed to prevent individuals from receiving exposures to radiation in excess of the limits in R313-15 of the UDRCR. While the electron beams produced by the particle accelerators are not that penetrating, the electron beam will create penetrating x-ray radiation that requires greater shielding. The concrete walls and ceilings of the sterilization cell will be in excess of 10 feet thick, and the product to be sterilized enters and leaves the cell via a serpentine pathway so that there is no straight pathway for radiation to escape the cell. Other penetrations into the cell, for purposes such as electrical wiring and ventilation, will also follow serpentine pathways.

The cell will be equipped with numerous, redundant interlocked safety systems designed to prevent entry into the cell while the particle accelerators are energized and producing radiation. Fresenius has also developed operating and emergency procedures to be implemented in addition to the physical and design features of the facility to ensure that

no one is exposed to radiation in excess of the limits in R313-15. Fresenius' vendor will be supplying the linear accelerators as well as technical expertise regarding the sterilization facility's design and operation.

As part of Fresenius' contract with its consultant company, a radiation survey of the sterilization facility with the E-beam equipment at full power will be completed prior to full production operations begin. Any problems detected during this survey regarding the adequacy of the facility's shielding will be corrected prior to the beginning of production operations.

R313-16-231(1)(c)

"The name and qualifications of the individual, appointed by the applicant, to serve as radiation safety officer pursuant to Section R313-35-140;"

Basis:

Fresenius has named Walter Evans as their RSO. Mr. Evans' training as RSO was completed during the week of November 12, 2004.

R313-16-231(1)(d)

"A description of the applicant's or the staff's experience in the use of the particle accelerators and radiation safety training; and"

Basis:

Fresenius currently has no one on staff with experience in operating particle accelerators. Fresenius has committed to hire a "technically skilled individual with e-beam experience" to begin their operations. In the event that Fresenius is unable to hire a person with the required training and experience, a technically qualified person will be hired and sent to an eight-day training course with Fresenius' consultant company. This individual and other operating personnel will also receive "on-the-job" training from the consultant for two weeks prior to actual production operations.

R313-16-231(1)(e)

"A description of the radiation safety training the applicant will provide to particle accelerator operators."

Basis:

The training of maintenance and operating personnel will be provided by Fresenius' consultant company. The training will cover: basic principles of electron beam technology, principles of sterilization, basic terminology and principles, system and equipment safety procedures, and operating procedures. Personnel will also initially have

approximately two weeks of "on-the-job" training on the E-beam equipment prior to the beginning of production operations. Fresenius personnel will have their initial training updated and reviewed annually. Fresenius maintenance personnel will receive additional training from the consultant during a five-day training course.

R313-16-231(2)

"Registrants who possess and use a particle accelerator that has been registered with the Department prior to January 1, 1999 shall submit a registration application that contains the information in Subsections R313-16-231(1)(a) through (e). The application shall be submitted by July 1, 1999."

Basis:

This rule is not applicable to this application.

Conclusion

Based upon the review of the application for registration submitted by Fresenius Medical Care, the Division has determined that the applicant has met the rule requirements for the issuance of a certificate of registration for their radiation producing machines. Per R313-17-2 of the URCR, the Division recommends that a public comment be opened regarding the issuance of a registration certificate to the applicant. Following the public comment period and the satisfactory response to any concerns raised during this period, the Division recommends that a certificate of registration be issued to Fresenius Medical Care.